

REMARKS

The Examiner is thanked for the due consideration given the application. This amendment is being filed concurrent with a Request for Continued Examination.

Claims 12-20 are pending in the application. Claims 12, 14, 15 and 17 have been amended to improve the language in a non-narrowing fashion. Claims 18-20 are new and find support in the drawing figures and further in claim 12 (regarding claim 20).

No new matter is believed to be added to the application by this amendment.

Claim Objections

Claims 12 and 14-17 have been objected to as containing informalities. The comments in the Official Action have been considered, and the claims have been amended to be free from informalities.

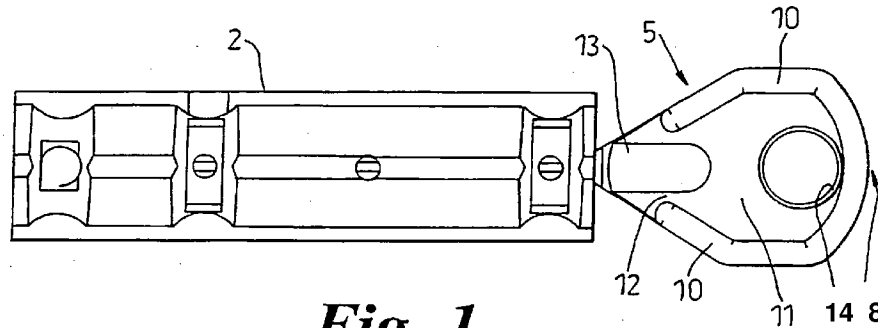
Art Rejections

Claims 12 and 14 have been rejected under 35 USC §103(a) as being unpatentable over MARSHALL et al. in view of MORITA. Claims 13 and 17 has been rejected under 35 USC §103(a) as being unpatentable over MARSHALL et al. in view of MORITA, and further in view of CROSSMAN. Claim 15 has been rejected under 35 USC §103(a) as being unpatentable over MARSHALL et al. in view of MORITA, and further in view

of HIGGINS. Claim 16 has been rejected under 35 USC §103(a) as being unpatentable over MARSHALL et al. in view of MORITA and HIGGINS, and further in view of CROSSMAN.

These rejections are respectfully traversed.

The present invention pertains to the design of a twist off cap or tab on a lancet that is illustrated, by way of example, in Figure 1 of the application, which is reproduced below.



In the present invention, a removable guard portion has an outer peripheral thickened rib describing a generally U- or C-shape. A central region is of thinner section than the rib and partly surrounded by the rib, and a tip encasing region encases the tip of the needle. The tip encasing region is of thicker section than the central region and is spaced from adjacent ends of the peripheral thickened region such that there are respective gaps therebetween bridged only by the thinner central section.

This structure is reflected in independent claims 12 and 15 of the present invention.

Newly presented claims 18-20 of the present invention also set forth embodiments where ends of the peripheral thickened rib are disposed laterally of the needle.

To recap on the innovative features of the present invention, the aim is to provide a specially shaped removable guard over the tip of the needle, which is integrally moulded with the remainder of the lancet body. An important issue at stake is that the needle needs to be very fine in order to minimise the user discomfort when pricking but the pressures involved in injection moulding are very high. This is an awkward combination because if, during moulding, the fine needle is subject to high off-axis force as the molded plastics material is forced under high pressure into the mould, the needle may be bent.

The inventor has designed a removable cap of a shape which is designed to choke down the speed of the intrushing molded plastic material during formation of the lancet. This is achieved by designing the removable guard portion so that it has a tip-encasing region (of relatively large cross-section) which encases the tip of the needle, a

central region of thinner section, and an outer peripheral thickened rib of U or C shape.

The tip encasing region is spaced from the adjacent ends of the peripheral thickened region so that there are respective gaps therebetween bridged only by the thinner central section. This means that, during formation, the molded plastics material may be supplied to that part of the cavity forming the peripheral rib (which is a relatively large cross section) to pass to the ends thereof where the cross sectional areas reduce or step down where the molten plastic has to pass through the thinner central region before opening out again into the larger dimensioned tip encasing region. In other words the peripheral rib forms an arcuate gallery into which the molten plastic rushes, with the thin gaps forming choke regions to decelerate the molten plastic as it enters laterally into the central thickened region around the needle tip.

Turning to MARSHALL et al., this reference pertains to a blood sampling device. The Official Action refers to Figure 1 of MARSHALL et al., which is reproduced below.

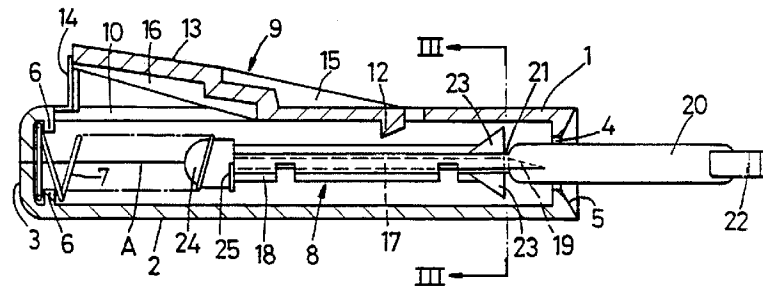


Fig.1

The features in Figure 1 of MARSHALL et al. include a cap 20 which passes freely through aperture 4 and terminates outside the body 1 in a tab 22 (Column 2, lines 56-57).

The Official Action also refers to Figures 10 and 11 of MORITA, which are reproduced below.

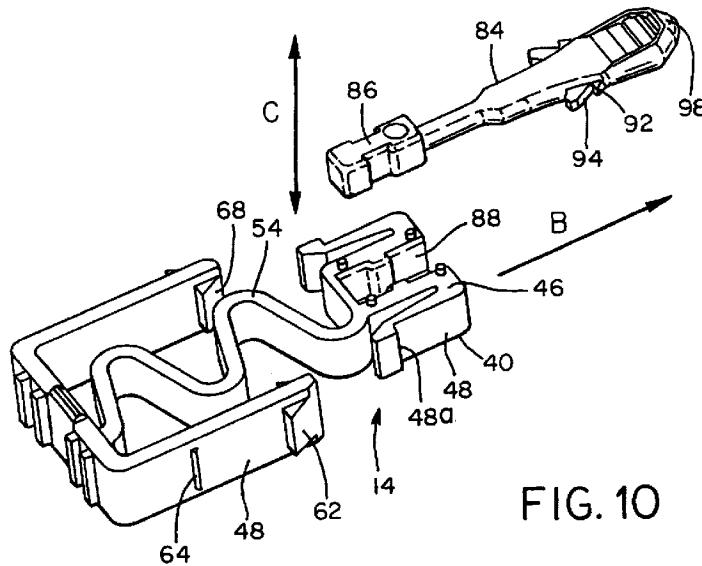


FIG. 10

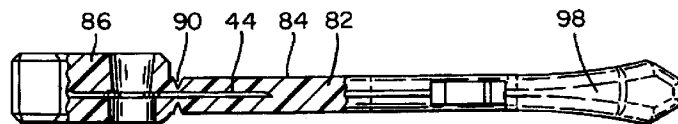


FIG. 11

Looking at the purported combination of MORITA with MARSHALL et al., the assertion that it would be obvious to add the slightly thickened peripheral rib of MORITA to the arrangement of MARSHALL et al. would not occur to one of ordinary skill. With its T-formation the MARSHALL et al. device already gives plenty of grip. Also the applicant can find no discussion in MORITA of the edge region enhancing the grip, as suggested in the Official Action, and the skilled person would have no reason to take this feature from MORITA. Indeed, MORITA makes no mention of the shape.

Even if a peripheral rib concept were applied to MARSHALL et al., the natural design would be to extend the peripheral rib so that it merged with the stem of the T of MARSHALL et al. In other words, by combining MORITA and MARSHALL et al., the resultant combination would be one which still failed to set forth the important feature that the ends of the peripheral region are spaced from the tip encasing regions by the regions of thinner section.

Furthermore, one skilled in the art, faced with combining MARSHALL et al. and MORITA would simply apply the head 98 of MORITA to the stem 20 of MARSHALL et al. rather than picking and choosing between the features of MORITA. Assuming this to be the case, then the stem 20 of MARSHALL

et al. combined with the head 98 of MORITA still fails to disclose the feature of gaps of thinner section between the tip encasing region and the thickened peripheral region. It will be recalled that in MORITA, there is no section corresponding to the "central region of thinner section" of the present invention. MORITA simply has a tip-encasing region, which extends way down to carry the thickened peripheral edge but without any step-down section as required by the claim.

There is additionally no teaching or inference of the ends of the peripheral rib being disposed laterally adjacent the needle, such as is set forth in new claims 18-20 of the present invention.

The other applied art references do not address the deficiencies of MARSHALL et al. and MORITA discussed above.

One of ordinary skill and creativity would thus fail to produce a claimed embodiment of the present invention from a knowledge of MARSHALL et al. and MORITA (and the secondary references). A *prima facie* case of unpatentability has thus not been made.

These rejections are believed to be overcome, and withdrawal thereof is respectfully suggested.

CONCLUSION

The rejections have been overcome, obviated or rendered moot, and it is believed that no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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